A Dissertation on

A PROSPECTIVE RANDOMIZED CONTROLLED STUDY ON COMPARISON OF WOUND HEALING WITH TYPE I COLLAGEN DRESSING & CONVENTIONAL DRESSING IN BURNS PATIENTS

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CERTIFICATE

This is to certify that **Dr. S. Raja, M.S.** Post Graduate student in General surgery, Government Kilpauk Medical College Hospital, attached to Government Kilpauk Medical College, Kilpauk, Chennai-10, carried out this dissertation titled

A Prospective Randomized Controlled Study on Comparison of Wound Healing with Type I Collagen Dressing & Conventional Dressing in Burns Patients

by himself under my guidance & direct supervision during the period of July, 2003 to September, 2006.

This dissertation is submitted to the Tamilnadu Dr. MGR Medical University, Chennai in partial fulfillment of the award of MS degree in General Surgery.

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INTRODUCTION

The ability of a living organism to repair the injuries sustained by it is the WONDER OF THE WORLD that always fascinates every body. The organized manner in which this occurs consists of wonderful cascade of events.

The study of wound healing has undergone dramatic changes within the last two decades. In the past, decisions regarding patient wound healing problems were made strictly on an empirical basis and based on historical observations and anecdotes, in some instances extending back millennia. Every materials & methods known to man has been tested or used to facilitate or accelerate the wound healing.

Nowadays we have various options before us to manipulate wound healing in many ways. Our renewed interest in wound healing has prompted a reappraisal of its **basic components** and how they are individually affected by biological, mechanical, and physical forces. The ultimate goal of clinical wound healing management is safe & easy manipulation of the healing process – we are closer to that goal than ever before.

The Healing of Skin – the largest organ of the human body is the most studied one. The Department of Burns, Plastic & Reconstructive Surgery in our Govt. Kilpauk Medical College Hospital receives the highest number of patients in the city affected with burns due to various causes. Here **Type I collagen dressing**, a form of **Biological Occlusive skin substitute wound coverage dressing** is being used regularly.

This study was conducted to *compare the wound healing* with collagen dressing and conventional dressing with ointment and gauze.

AIM OF STUDY

This Prospective Randomized Controlled study was conducted to *compare the wound healing* with collagen dressing and conventional dressing with ointment, gauze-pad & bandage, with respect to the following criteria:

- Their efficacy on wound healing in Burns patients
- The ability to prevent infection
- The effect on the morbidity
- The cost effectiveness

WOUNDS AND THEIR MANAGEMENT

The past 2 decades have produced more advances in wound care than have the previous 2000 years as a result of rapid expansion in the knowledge of the healing process at the molecular level. The coordinated interplay of technology and expanding scientific knowledge has provided wound-care methods that have greatly improved the ability to heal wounds with few complications. These advances serve as a prelude to the impetus that is likely to come in the future.

Two broad categories exist for the **classification of wounds: Chronic and acute**. *Acute wounds* undergo a complex interactive process involving a variety of cell types that leads to a healed wound. Conversely, *chronic wounds* have proceeded through portions of the repair process without establishing a functional anatomic result.

The ability to heal an injury is a biologic necessity for all organisms, with mammals lagging in proficiency when compared with lower life forms that have the ability to regenerate differentiated structures. Technology and increased scientific knowledge have established a coordinated interplay that has improved the ability to manage wounds in a logical manner, and, on occasion, to accelerate the healing process. **Insight into the complex chain of events leading to the formation of scar is a necessity for every individual who attempts wound management**.

Although the wound-healing process varies among different tissue types, there are more similarities than differences between them. *In this discussion, skin is considered as a representative tissue type*. There are also different types of acute skin wounds, including incisional wounds, partial thickness injuries (Burns) and wounds involving significant tissue loss. Different types of wounds involve different phases of the healing process to varying degrees, although the phases themselves remain the same.

PHASES OF WOUND HEALING

Healing of an acute wound follows a predictable chain of events. This chain of events occurs in a carefully regulated fashion that is reproducible from wound to wound. The phases of wound healing are overlapping, but are described in a linear fashion for the purpose of clarity.

The five phases that characterize wound healing include

(1) hemostasis,

(2) inflammation,

(3) cellular migration and proliferation,

(4) protein synthesis and wound contraction, and

(5) remodeling.

(1) HEMOSTASIS

All significant trauma creates a vascular injury and thereby initiates the molecular and cellular responses that establish hemostasis. The healing process cannot proceed until hemostasis is accomplished. Primary contributors to hemostasis include vasoconstriction, platelet aggregation, and fibrin deposition resulting from the coagulation cascades. The end product of the hemostatic process is clot formation.

(2) INFLAMMATION

Though they were described in an Egyptian Papyrus (3000 BC), Celsus, a Roman writer of the first century AD first listed the four cardinal signs of inflammation: rubor, tumor, calor, and dolor (redness, swelling, heat, and pain). A fifth clinical sign, loss of function (functio laesa), was later added by Virchow. In 1793, the Scottish Surgeon John Hunter noted: that inflammation is not a disease but a non-specific response that has a “salutary” effect on the host.

At the tissue level, increased vascular permeability and the sequential migration of leukocytes into the extravascular space characterize inflammation. One of the primary functions, of inflammation is to bring inflammatory cells to the injured area. These

cells then destroy bacteria and eliminate debris from dying cells and damaged matrix so that the repair processes can proceed.

Within 10 to 15 minutes after injury, the endothelial cells lining the capillaries in the vicinity of the wound develop gaps between them, which permit the leakage of plasma from the intravascular space to the extravascular compartment. The migration of fluid into the injured area generates edema, which contributes to the sensation of pain that characterizes inflammation.

As the healing process proceeds, inflammatory cells trapped within clots are sloughed. **Neutrophils remaining within the wound become senescent and undergo apoptosis**. **The stimuli that lead to inflammatory cell apoptosis during tissue repair and scar formation have yet to be determined**. Neutrophils are the first of the inflammatory cells to become apoptotic. They are then phagocytosed by macrophages. Macrophages and lymphocytes remain in the wound for approximately 7 days and then gradually diminish in number unless a noxious stimulant of further inflammation persists. Inflammatory cell apoptosis influences antigen presentation and probably more importantly, contributes to modulation of cytokine concentrations.

Cytokines

The wound-healing process is, in large part, regulated by the ordered production of cytokines that control gene activation responsible for cellular migration and proliferation and synthetic activities. As mentioned, platelets and macrophages are key cytokine sources, although many other cells produce them.

(3) CELLULAR MIGRATION AND PROLIFERATION

The cellular milieu in wounds changes dramatically in the first week post acute injury. The initial fibrin-fibronectin matrix is heavily populated by inflammatory cells, whereas fibroblasts and endothelial cells will predominate as healing progresses.

Re-establishment of the epithelial surface is also initiated within the first several days after injury, as is revascularization of the damaged area. Cytokine networks continue to be a part of the process as cytokine release contributes to fibroplasias, epithelialization, and angiogenesis. Although much is known about the signals that stimulate the predominant activities during this phase of healing, **less is known about the signals that bring these activities to a controlled end**. Negative feedback mechanisms that deactivate cells after they have completed their work are also essential for normal healing.

Additional fibroblasts are required in the healing wound, in that native cells are lost or damaged in any injury. Repopulation of the wounded area with fibroblasts occurs as a result of fibroblast migration from adjacent tissues and proliferation of cells in the wound. In addition, undifferentiated cells in the vicinity of the wound may transform into fibroblasts under the influence of cytokines in the wound milieu

Angiogenesis

The angiogenic process becomes active from day 2 after wounding. Factors in the wound milieu that contribute to angiogenesis include high lactate levels, acidic pH, and, in particular, decreased oxygen tension. The severe degree of hypoxia in granulation tissue most likely results from both disruption of the native vasculature and increased oxygen consumption by cells in the wound environment. Proliferating cells are known to consume oxygen three to five times faster than do cells in resting phases of the cell cycle.

During angiogenesis, endothelial sprouts derive from intact capillaries at the wound periphery. The sprouts grow through cellular migration and proliferation. The endothelial cells develop a curvature and begin to produce a lumen as the chain of endothelial cells elongates. Eventually, the endothelial sprout comes into contact with

a sprout derived from a different capillary, and they interconnect generating a new capillary.

Epithelialization

Following acute injury, reconstruction of injured epithelium is crucial for re-establishment of the barrier functions of the skin. Reconstruction of injured epithelium begins almost immediately after wounding. Incisional skin injuries, with a minimal epithelial gap, after initial injury, although larger wounds can take much longer to regenerate a neoepithelium.

During the first 24 hours after injury, basal cells present at the wound edge elongate and begin to migrate across the denuded wound surface. If the initial injury does not destroy epithelial appendages such as hair follicles and sweat glands, these structures also contribute migratory epithelial cells to the healing process. These cells migrate across the wounded area essentially as a monolayer. Approximately 24 hours after the initiation of cellular migration, basal cells at the wound edge and in the appendages, if present, begin to proliferate, contributing additional cells to the healing monolayer. The migration of epithelial cells continues until overlap is achieved with other epithelial cells migrating from different directions. At that point, “contact inhibition” results in cessation of cellular migration.

If the epidermal basement membrane is intact, cells simply migrate over it. In wounds in which it has been destroyed, the cells initially begin to migrate over the fibrin-fibronectin provisional matrix. As they migrate across the matrix, however, epithelial cells regenerate a new basement membrane. Re-establishment of a basement membrane under the migrating cells involves the secretion of tenasin, vitronectin, and type I and V collagens.

When contact inhibition is achieved, hemidesmosomes re-form between the cells and basement membrane, and tenasin and vitronectin secretion diminishes. The cells become more basaloid, and further cellular proliferation generates a multi-laminated **neoepidermis** covered by keratin. The neo-epidermis is similar to the native epidermis, although it is slightly thinner, the basement membrane is flatter, and rete pegs that normally penetrate the dermis are absent.

(4) PROTEIN SYNTHESIS AND WOUND CONTRACTION

Synthesis and deposition of proteins and wound contraction are the wound-healing events that begin to predominate 4 to 5 days after wounding. The quality and quantity of matrix deposited during this phase of healing significantly influence the strength of a scar. Collagen constitutes more than 50% of the protein in scar tissue, and its production is essential to the healing process. Fibroblasts are responsible for the synthesis of collagen and other proteins

regenerated during the repair process. Collagen synthesis is also affected by characteristics of the patient and the wound including age, tension, pressure, and stress. Collagen synthesis continues at a maximal rate for 2 to 4 weeks and subsequently begins to slow.

Conversely, keloid formation results from excessive collagen synthesis for which a preventative measure has yet to be found.

As mentioned, the initial wound matrix is composed primarily of fibrin and fibronectin. As protein synthesis accelerates, the nature of the wound matrix changes. Collagen and other proteins such as proteoglycans gradually replace fibrin as primary matrix constituents. Proteoglycans are a key component of mature matrix and are actively synthesized during this phase of healing.

Collagen makes up 25% of protein in the body and more than 50% of protein in scar tissue. The concentration of collagen subtypes varies among tissues. **Type I collagen predominates and makes up 80% to 90% of the collagen seen in intact dermis**. The remaining 10% to 20% is type III collagen. In contrast, granulation tissue that forms soon after injury contains 30% type III collagen. Accelerated type III collagen synthesis is correlated with fibronectin secretion after injury. Type II collagen is seen almost exclusively in cartilage, whereas type IV collagen is found in basement membranes. Type V

collagen is found in blood vessels, whereas type VII collagen forms the anchoring fibrils of epidermal basement membrane.

Type I collagen consists of a triple helix involving three polypeptide chains that are synthesized separately within the fibroblast. The polypeptide chains consist of a repeating glycine-X-Y pattern, in which the X position is often proline and the Y position is often hydroxyproline. The interaction of chains initiates the formation of the triple helix, which is secreted as **"procollagen"** into the extracellular environment. Collagen undergoes eight post-translational steps intracellularly prior to its extracellular secretion in the form of procollagen

Wound contraction begins 4 to 5 days after initial injury and actively continues for approximately 2 weeks. The process continues for a longer period of time in wounds that remain open at the end of the 2-week interval. In an open wound, the results of wound contraction are evident because wound edges draw closer to each other. In an incisional wound, wound contraction simply results in scar shortening and is less apparent. The rate of contraction varies between anatomic locations, but averages approximately 0.6 to 0.7 mm per day. The rate of contraction can often be predicted by the degree of skin laxity at the wound site. A wound on the scalp or pretibial area will contract significantly more slowly than a buttock

wound. Wound shape also affects the rate of contraction, with square wounds contracting more quickly than circular wounds. Circular stomas are therefore less likely to have compromised patency secondary to contraction.

Wound contraction is characterized by a predominance of myofibroblasts at the wound periphery. Myofibroblasts are modified fibroblasts that were initially described by Gabbiani et al in 1971. The defining characteristics of myofibroblasts include actin-rich microfilaments in the cytoplasm, a multi-lobulated nucleus, and abundant rough endoplamic reticulum that can only be discerned by electron microscopy. The time frame in which myofibroblasts are present within the wound does not correspond perfectly to the course of wound contraction, although it is fairly close. Myofibroblasts appear 4 to 6 days after initial injury and are commonly seen in the wound during the ensuing 2 to 3 weeks. Their disappearance is suspected to be via apoptosis.

Although Gabbiani et al postulated that these cells were the “motor” that contracted a wound; more recent work with collagen lattices has suggested that fibroblasts in the central portion of the wound may be more critical to the contraction process. It is clear, however, that the process of wound contraction is cell mediated and

does not require collagen synthesis. TGF-beta and possibly other cytokines are involved in the wound contraction process.

Wound contraction is sometimes not a desirable healing event. Wound contraction across joints can produce **contractures** that significantly limit function. In cases in which contraction inhibition is preferred, skin grafting, especially with thicker grafts, is used to limit contraction. Splints can also limit undesirable contraction in certain anatomic locations if utilized for prolonged periods.

(5) REMODELING

Scar remodeling begins to predominate as the primary wound-healing activity approximately 21 days after injury. The rate of collagen synthesis diminishes and reaches coincidence with the rate of collagen breakdown. The down-regulation of collagen synthesis is mediated by gamma-interferon, TNF-alpha, and collagen matrix itself.

The nature of the wound matrix changes with scar remodeling. Immature scar contains a disorganized array of fine collagen fibers, which is gradually replaced by thicker fibers arranged in an orientation paralleling skin stresses. In addition, the number of cross-links both within and between molecules gradually increases. As the nature of the collagen matrix changes, it becomes less cellular through apoptosis of cells involved in the healing process. As mentioned, the

ratio of type I to type III collagen changes, and the quantity of water and proteoglycans diminish. **Normal skin shows a basketlike weave pattern that is never completely reproduced with scar remodeling.**

Although seemingly not as complex as other aspects of the healing process, remodeling is essential to the formation of a strong wound. The remodeling process is associated with a substantial increase in wound-breaking strength. Wound strength 1 week after injury is 3% of normal dermis. After 3 weeks, when the remodeling phase begins to predominate, the wound will have only approximately 20% of the strength of normal dermis. At 3 months, however, the wound will have 80% the strength of normal dermis, with the significant increase in strength resulting from the contribution of remodeling. Remodeling will continue for up to 12 months after a wound is created, although scars never regain the strength of normal dermis.

DRESSINGS

Dressings have been used since antiquity to facilitate the healing process. The choice of which dressing to use for a particular wound requires an understanding of tissue repair and knowledge of the properties of available dressings. There are currently hundreds of dressings on the market to aid in wound management.

Before selecting a dressing for a particular wound, a practitioner must assess carefully the needs of the wound to understand which dressing would provide maximal benefit. Frequently, there is not one clear best choice, and it is crucial that the pros and cons of each dressing modality be understood**.**

Brief history of dressings

Historically, wounds were treated with homespun remedies derived in part from ritualistic teachings and in part from careful observation. Almost every methods and materials known to man have been tried on the wound for enhancing wound healing. **The "three healing gestures"** were described (circa) 2200 BC on an ancient clay tablet:

(1) washing the wound,

(2) making plasters (mixtures of herbs, ointments, and oils that were applied to wounds to aid in the healing process), and

(3) bandaging the wound.

The first antiseptic dressings were introduced in 1967 by Lister, who soaked lint and gauze in carbolic acid (phenol) before applying them to wounds. True sterilization did not become a available until nearly the turn of the twentieth century, however. One of the earliest nonadherent dressings was tulle gras, which gained popularity in World War I and consisted of **gauze impregnated with paraffin**. Owens first discussed fine mesh gauze as a minimally adherent intermediary underlying more absorptive materials in 1944.

Many sophisticated dressings have become available to the wound care practitioner more recently. These newer materials and agents supplement older dressing materials, such as gauze, which still are commonly used. *The decision of which dressing to use for a particular wound can be challenging given the array of products available*.

Desirable dressing characteristics

Certain features are desired in a dressing regardless of its structure and the type of wound on which it is placed, as follows:

- Protect wound from bacteria and foreign material
- Absorb exudates from wound
- Prevent heat and fluid loss from wound
- Provide compression to minimize edema and obliterate dead space
- Be nonadherent to limit wound disruption
- Create a warm, moist occluded environment to maximize epithelialization and minimize pain
- Be esthetically attractive

All dressings ideally should protect wounds from trauma and contamination by bacteria and foreign material. Dressings also should absorb exudates generated by the wound. Another priority is to provide compression to minimize edema and obliterate dead space. In most circumstances, *maintenance of a warm, moist environment is desirable to maximize the rate at which healing functions occur*. Prevention of heat and fluid loss is also important, especially in wounds covering a large surface area, such as burns. Nonadherence

is generally desirable to limit disruption of healing tissues during dressing changes. All dressings should be esthetically attractive.

No single dressing can provide all of these functions optimally, and not all functions are required for all wounds. Different dressing materials provide different functions to greater or lesser degrees, and the *attributes of each dressing material need to be matched to the specific wound on which it is placed*.

An alternative to the application of a dressing is simply allowing a scab to form on a wound. **Scabs are nature's dressing**. Essentially, they are crusts of dried serum with trapped erythrocytes, platelets, and other blood-borne cells. *Scabs provide many functions often provided by dressings*, including

- provision of a barrier against foreign material,
- reduction of pain,
- holding the wound edges in approximation,
- facilitation of wound contraction, and
- minimizing the loss of fluid and proteins.

Although scabs perform many useful functions, they are not ideal. *They slow epithelialization, and they can fix bacteria on the wound surface, which can lead to infection*.

SPECIAL WOUND REQUIREMENTS

In some wounds, factors may be present that interfere with normal healing. In these situations, the need for a warm, moist occluded environment may be superseded by the need to eliminate the factors interfering with normal healing. As mentioned, wounds related to infection and wounds that are heavily contaminated by bacteria require a dressing that diminishes the bacterial count in the wound. Placing an occlusive dressing on an infected wound encourages bacterial proliferation and exacerbates the infection.

Heavily exudative wounds often require a degree of absorption that no occlusive dressing can provide. Large amounts of exudates can macerate the skin surrounding a wound and dilute intrinsic factors such as cytokines, which promote healing. Absorption of excessive exudates becomes a priority in these wounds.

Dressing regimens that contribute to wound debridement are required in wounds containing nonviable tissue. Similar dressings are required in wounds with foreign bodies or debris. In wounds involving toxins, such as brown recluse spider bites or infiltrated chemotherapeutic agents, debridement is required to limit ongoing damage by the toxic agent, although surgical debridement generally is required in these scenarios.

For wounds requiring extensive debridement, nothing surpasses surgical debridement in terms of effectiveness. In wounds in which the surgical approach cannot be use4d because of coexisting morbidities or in which the tissue requiring debridement is less defined, wet-to-dry dressing changes or enzymatic agents have utility. Enzymatic debridement may be slightly more comfortable for the patient, but it involves additional costs.

TYPES OF DRESSINGS

As mentioned previously, no single dressing can provide all things to all wounds, and the needs of each individual wound need to be prioritized. These needs must be matched to the pros and cons of possible dressings. Frequently, there is not one clear best choice, especially because most wounds have a variety of needs. The practitioner must decide which dressing functions to maximize to choose among the possibly acceptable dressing candidates.

Dressings can be classified based on their construction and function.

Types of dressings

Nonadherent fabrics	Occlusive
Absorptive	Nonbiologic
Gauze	Films
Foams	Hydrocolloids
Creams, ointments, and solutions	Alginates
Antibacterial	Hydrogels
Enzymatic	Biologic
Others	Homograft
	Xenograft
	Amnion
	Skin Substitutes

I. NONADHERENT FABRICS

Nonadherent fabrics are derivatives of fine mesh owen gauze and tulle gras. Many of the dressings in this category consist of fine mesh gauze with a supplement provided to augment its occlusive properties, its nonadherent properties, its healing facilitating capabilities, or its antibacterial characteristics. There are also synthetic nonadherent fabrics.

Nonadherent fabrics can be divided into hydrophobic and hydrophilic dressings. **Hydrophobic fabrics** are more occlusive, eg. Vaseline gauze. These materials do not facilitate the drainage of fluid through them readily. **Hydrophilic materials** incude eg. Fine mesh gauze. These materials more readily facilitate the drainage of fluid into overlying dressing layers.

II. ABSORPTIVE DRESSINGS

Absorption of exudates is a desirable dressing attribute. A study showed that exudates production from leg ulcers averages about 5 g/10 sq.cm/24h (range. 4 to 12 g/10 sq.cm/24h). Exudate collects and contributes to wound maceration if not wicked away from the wound surface.

Gauze

Wide mesh gauze is excellent at wicking exudates away from a wound, although it loses effectiveness when saturated. Gauze commonly is placed over nonocclusive, nonadhering fabric dressing materials to absorb material draining through them. Wide mesh gauze adheres to a wound if placed in direct contact with it. Although disadvantageous for most wounds, this characteristic can be advantageous if wound debridement is desired.

Foams

Foam dressings consist of hydrophobic, polyurethane foam sheets. The advantages of foam dressings are that they are absorbent and nonadherent, and they can expand and conform to wounds with unusual configurations. They are comfortable and can be removed easily for cleaning.

Foam dressings have disadvantages as well. As wounds heal, they need to be replaced with additional dressings that correspond in size to the shrinking wound. Also, they provide limited protection from bacterial contamination. Because they absorb fluid from the environment, they cannot be used while bathing.

Epithelialization does not occur as readily under foam dressings as under occlusive dressings. This may be a result of less precise occlusion or possibly mechanical impairment of keratinocyte migration created by the irregular foam surface. In addition, the wicking property of foams may leach cytokines from the wound surface.

III. CREAMS, OINTMENTS, AND SOLUTIONS

Many topical wound treatments are available in the form of creams, ointments, and solutions. This is a broad category that extents from time-honored materials, such as zinc oxide paste, to cutting-edge preparations containing growth factors. Ointments commonly are used on the face, where creams have a greater tendency to run in to the eyes or mouth.

The primary advantage to this approach is that it is simple and does not interfere with function. Ointment also provides a moist environment, which facilitates epithelialization and limits scab formation. The disadvantages of this approach are that it provides limited absorption, protection, immobilization, and compression. Also the ointment can be wiped off inadvertently. If excessive ointment is applied to a wound, it sometimes can become macerated as well.

Many of the creams, ointments, and solutions are designed to have antibacterial properties. Others include enzymatic debriding agents. Still others include free radical scavengers (allopurinol, dimethyl sulfoxide), agents to degrease platelet aggregation (iloprost), and growth factors (platelet-derived growth factor) or agents that bind growth factors (sucralfate).

Silver-based dressings - Silver sulfadiazine

Silver sulfadiazene (Silvadene) was developed in the 1960s by Fox. Silvadene has a broad spectrum of antibacterial, antifungal, and aniviral activity. Its limitations are its occational association with a transient neutropenia and its occasional topical sensitivity. Although fibroblast toxicity has been shown for Silvadene and Sulfamylon in culture, it has been noted to accelerate epithelialization of partial-thickness wounds, suggesting that some of the toxicity may be buffered by other wound components in vivo. In other studies, an increase in neovascularization was noted. Silvadene has become the most commonly used antibacterial agent in burn wound management. For most bacterially contaminated wounds also, Silvadene is the preferred antibacterial in that it is effective against a broad spectrum of bacteria and has minimal toxicity.

IV. OCCLUSIVE DRESSINGS

Currently, occlusive dressings can be divided into two classes, **non-biologic** and **biologic**. Nonbiologic occlusive dressings include films, hydrocolloids, alginates, and hydrogels. Depending on their construction, some foam dressings fit in this category as well. Biologic occlusive dressings include allograft, xenograft, amnion, and skin substitutes.

Concept of occlusion

Understanding the concept of occlusion has been fundamental to the evolution of wound dressings and has created a paradigm shift in the management of wounds. Before this understanding, wounds often were kept dry, as advocated by Pasteur to keep them “germ-free”. Winter published his seminal work on the effects of occlusion on the rate of epithelialization in 1962. In his porcine model, surgically created wounds were left to heal either open to air or occluded under a transparent film. **The rate of epithelialization under the occlusive dressing was twofold that of the wounds left undressed.**

(1) Occlusive dressings limit the transmission of fluids, water vapour, and gasses from the wound bed to the external environment. In general, a moisture vapour transmission rate less than 35 g of water vapour transmitted per square meter of dressing per hour is

considered low enough to maintain a moist environment on the surface of most wounds.

Moisture prevents desiccation, which leads to cell death. Moisture also facilitates epidermal migration, angiogenesis, and connective tissue synthesis. In addition, it supports autolysis of necrotic material by providing the solute for enzymatic debridement.

(2) By maintaining an occluded moist environment, these dressings maintain a mildly acidic pH and a relatively low oxygen tension on the wound surface. These wound characteristics mirror the usual early wound environment. A steep oxygen gradient stimulates angiogenesis, an important factor in wound healing. A low oxygen tension also provides optimal conditions for fibroblast proliferation and granulation tissue formation.

(3) Granulation tissue formation and epithelialization also are encouraged by cytokines, which are more likely to be preserved in an occluded wound environment.

(4) Occlusive dressings limit the pain associated with partial-thickness wounds to a much greater degree than non-occlusive dressings.

Films

Film dressings are generally clear polyurethane membranes with acrylic adhesive on one side for adherence. Eg. Opsite. They are waterproof but allow the transmission of oxygen, carbon dioxide, and water vapour. The degree of permeability varies with the product. Because they are generally transparent, the underlying wounds can be visualized easily, and because they are extremely thin, they do not interfere with patient function.

Film dressings have disadvantages as well. They are nonabsorptive so that exudate collects under them and frequently leaks out. This leaking disrupts the antibacterial seal created by the dressing in addition to being messy. Dressing changes frequently are required when this occurs. Another disadvantage is that there need to be intact skin surrounding the area being dressed for dressing adherence. **This skin may not be available when large donor sites are needed, as in burn patients**. Wound contraction may be slowed by occlusive dressings, and removal of the dressings can disrupt new epithelium.

Hydrocolloids

The term hydrocolloid is used to describe a family of dressings containing a hydrocolloid matrix composed of such materials as

gelatin, pectin, and carboxymethylcellulose. Hydrocolloid dressings are available as adhesive wagers or as pastes or powders. On contact with wound exudates, the matrix absorbs water, swells, and liquefies to form a moist gel. Products vary in absorption capacity and may or may not leave a residue in the wound. The ability of hydrocolloids to absorb wound exudates differentiates them from films. Otherwise, they share many positive characteristics, including limited moisture and gas transmission and impermeability to bacteria.

Hydrocolloids are generally opaque and are slightly bulkier than films. This increased size may provide more protection for the wound, although it may interfere with function to a greater degree.

Alginates

Alginate dressings are composed of soft, nonwoven fibers of a cellulose-like polysaccharide derived from the calcium salt of alginic acid (seaweed). They have their primary utility in exudative wounds. When in contact with wound exudates, the insoluble calcium alginate is partially converted to a soluble sodium salt. This conversion generates a hydrophilic gel as a by-product. The gel creates an occlusive environment that facilitates healing. The characteristics of the environment under alginate dressings have not been evaluated as completely as that under films and hydrocolloids. When the alginate becomes engorged and begins to “bleed”, a dressing change is

indicated. Alginates are packaged in a variety of forms, including ropes for packing cavities, ribbons for narrow wounds or sinuses, and pads.

Hydrogels

Hydrogel dressings consist of a starch polymer, such as polyethylene oxide, or a carboxymethylcellulose polymer and upto 80% water. They are available as gels, sheets, or impregnated gauze. They function as rehydrating agents for dry wounds. Because of their high water content, they do not absorb large amounts of wound exudates. They do create an occlusive environment underneath them, although the characteristics of the environment have not been well worked out.

COMPARISONS OF NONBIOLOGIC OCCLUSIVE DRESSINGS

There are significant differences between different types of nonbiologic occlusive dressings. There are also differences between different products in each category. Although similar in appearance, the dressings differed markedly. Thickness, absorption, moisture vapour permeability, conformability, residual supernatant pH, fluid retention, and gel cohesion all varies from product to product. There are significant differences in the levels of occlusion produced.

Bradley and coworkers performed a meta-analysis of dressings and topical agents used for pressure sore treatment. **No significant differences** were noted between polyurethane foam dressings, film dressings, hydrocolloid dressings, or various membrane dressings **in their effects on healing**.

Although there are differences in handling characteristics, adherence, dispersion of wound exudates, and amount of dressing residue left on the wound, **they do not differ significantly in their effect on epithelialization or dermal healing.**

There is evidence that each of the occlusive dressings facilitates healing and limits pain to a greater degree than non-occlusive dressings. It is difficult to state that one occlusive dressing provides these attributes better than another, however. The choice of which occlusive dressing to use for a particular wound is predicated primarily on other factors. Hydrocolloid and alginate dressings generally provide more absorption than either hydrogel dressings, which provide limited absorption, or films, which are non-absorptive.

Films are transparent and allow wounds to be visualized. None of the other occlusive dressings provide this benefit. The film and hydrocolloid dressings include adhesives. They generally adhere better than hydrogels or alginates but require surrounding skin that is intact to which to adhere. This ability to adhere allows films and

hydrocolloids to protect wounds better from contamination by bacteria and foreign materials but may contribute to more disruption of healing tissues with dressing changes.

Biologic occlusive dressings

As mentioned, biologic dressings include homograft, xenograft, and amnion. Homograft is a graft transplanted between genetically unique humans, whereas a xenograft is a graft transplanted between species. Pigskin is the most commonly used xenograft. Homografts and xenografts are **temporary dressings** in that both are rejected if left on a wound for an extended period. Amnion is derived from human placentas and is another effective biologic wound dressing. Its use has diminished with increased concern regarding biologic materials.

Wound Coverage vs Wound Closure

Wound closure materials are biologically accepted by the wound bed & become permanently incorporated into the healing wound. On the other hand, wound Coverage materials rely upon incorporation into the wound coagulum & ingrowth of granulation tissues for adhesion; this phenomenon is characteristic of many wound coverage materials. These materials in general do not biodegrade & therefore they can only be temporary substitutes & must be replaced with the patient's skin either by re-epithelialization or skin grafts. In the case of temporary coverage, the wound should not be colonized with bacteria

& it should be sufficiently superficial that it is expected to heal completely within 3 weeks. Epithelial cells from the epidermal appendages grow & replace the destroyed epidermis and gradually the wound coverage material is shed. Therefore, the primary goals for the wound coverage materials in Superficial Second degree wounds are: to limit the microbial invasion of the wound bed (microbial barrier) & thereby to prevent infection; to limit the access of air & thereby to minimize pain.

Wound coverage materials have been used temporarily for deep second or third degree injuries prior to definitive wound closure with autologous skin in Patients with massive burn injuries. Unfortunately, this strategy frequently fails because underlying devitalized burn tissues routinely lead to contained infections when used with these deeper burn injuries.

Eg. Of wound coverage materials include Tegaderm, Biobrane & porcine skin Xenografts.

	Wound coverage	Wound closure
Biologically acceptable to the wound bed	temporary	permanent
Incorporates into the healing wound	No*	Yes
Prevents formation of Granulation tissue	No	Yes
Biodegrades	No	Yes
Useful in superficial wounds^	Yes	+/-
Undergoes transepithelial elimination#	Yes	No

* Incorporates into wound coagulum & granulation tissue

^ Wounds exposed to completely heal within 3 weeks

The new epidermis migrates between the foreign material & eliminates it

Wound closure Materials:

Dermal matrix strategy – eg. Biobrane, Integra, Eucoll, Healicoll (totally acellular)

Composite materials stragegy – eg. Trancyte, Apligraf.

Cultured Cells

COLLAGEN DRESSING

INTRODUCTION

Collagen is a biological protein with a unique chemistry and multiple physiological functions. It is a natural biomaterial, which has many responsibilities in the body, such as aiding cellular activity and providing an organized matrix in most tissues including skin.

Collagen is a large protein molecule (app. 300,000mw) containing simple amino acids like alanine, glycine and hydroxyproline. Among the different types of Collagen, **Type-I collagen is known to be less antigenic**. At molecular level, collagen tends to attract undifferentiated stem cells and convert them into appropriate cell types for proper remodeling of the tissue under repair. Its unique chemical, structural, mechanical and physical properties form an environment conducive to wound healing and ultimately wound closure, thus making it the most ideal natural biomaterial of choice, in health care.

Collagen has been used as filling material for orthopaedic applications and in different forms for dental applications. Collagen shields and gels have been extensively used for various ophthalmological applications. It is also used as a hemostatic agent besides being used as various prosthetic implants.

There are two types of collagen sheets are commonly available in the market for wound covering. **Wet collagen** was the one first

introduced. It was stored and transported in FORMALIN. Therefore it has to be washed well with normal saline before application on the wound. Otherwise, there will be severe burning sensation. **Dry collagen** came into the market later. This has the advantage of direct application over the wound without the need of washing with saline.

COMPARISON

Type	Drawback/Advantage
Synthetic dressing Eg. Paraffin Gauze, Polyurethane dressings	Non-biologic, Non-bioactive Needs repeated dressing
Natural dressing Plant: eg. Alginate dressings	Non-bioactive, Non-resorbable Limited application
Biological: Wet Collagen	Needs preparation before application. (to be pre-washed)
Dry-Collagen (Healicoll)	Ready to use, ease in application, flexible & tackiness, cover the wound properly, ease of application. Being transparent enables monitoring of the wound without disturbing the healing process. Provides hemostasis, High patient comfort, Economical

What is **Healicoll-M**?

- It is commercial product of DRY COLLAGEN produced by Advanced Biotech Products (P) Ltd. (They can be contacted @ www. advancedbiotech.org)
- It is the reconstituted collagen sheet free of contaminants like lipids, elastin and other immunogenic proteins.
- It is derived from selected animal tissues, using a patented process from US to obtain high quality collagen type I.
- It is processed under GMP conditions and stringent USP quality test as per international standards.
- It is transparent and dry membrane with unique advantage of flexibility and moderate tackiness.
- It is presented with a backing sheet, individually packaged in synthetic micro porous paper pouch and is gas sterilized

Directions of Use

- No pre-treatment is needed for application of dry collagen (Healicoll) or wet collagen. It is ready to apply.
- Clean the application site thoroughly with povidone iodine or any other antiseptic.

- Do not apply ointment or any greasy cream on the site prior to dry collagen
- Peal open the pouch and directly apply the collagen on the cleaned wound. *Do not mesh the collagen*.
- Do not try to over stretch the membrane.
- You can apply collagen on either of its surface and it adheres to the wound instantly.
- In case of dry wounds, sprinkle sterile saline solution on the surface and apply.
- Gently press the membrane with gauze soaked in saline, especially around the edges for better adhesion.
- Repeated dressing is not required, unless the wound is infected.
- Collagen wound cover is transparent – hence we can monitor the healing – without peeling off the membrane and thus avoid disturbing epithelialization.
- The collagen peels off as the wound heals. However, in some circumstances it may need to be moistened with saline before removal.
- In **ulcers**, the necrotic tissue should be removed and the sheet should be applied on granulation of the tissues.

- In case of localized bulging of collagen after application due to **fluid** accumulation beneath, a small incision can be made at the site and exude the fluid. This incision can be sealed with additional small piece of collagen, which adheres firmly with the already applied sheet. Alternatively, to avoid such inconvenience, meshed type of collagen is also available, where the excess fluid is released automatically. The same can be used for **donor site** application also.

- For **donor site application**, after surgical removal of donor tissue, arrest bleeding by conventional methods, clean the site and apply collagen. This avoids repeated dressing.

- Concurrent systemic therapy may be given as prescribed in infected cases, leprosy and non-infected cases for better and faster results.

Uses:

As Single Application

- First or Second degree burns
- Non-infected or Pre-cleaned burns
- Trauma with skin loss
- Chronic skin ulcers
- Skin donor sites
- Amputation sites

Repeated Application

- Covering material for bedsore
- Diabetic and other type of ulcers

REVIEW OF LITERATURE

1. CONVENTIONAL DRESSING

The traditional approach of dressing is to use three layers – a contact layer, an absorptive layer, and a binding layer. The **contact layer** is the layer in contact with the wound itself. A nonadhering, hydrophilic material, is optimal to facilitate drainage into the overlying dressing layers and minimally interfere with healing tissues. The second **absorptive layer** generally consists of gauze-pad that wicks wound exudates away from the wound to limit maceration. The outer **binding layer** fixes the dressing in place and may provide compression and immobilization. Tape is most commonly used.

The advantages of the three-layer dressing are that it protects the wound and absorbs wound exudate well. Wound compression and immobilization can be provided to a variable degree depending on the binding layer used. There are several disadvantages to this approach, however. The relatively dry environment is not optimal for wound reepithelialization. The dressings frequently are bulky and cumbersome for the patient. The dressings cannot handle an unlimited amount of drainage and lose their effectiveness if they soak through.

2. COLLAGEN DRESSING

Collagen is a biological protein with a unique chemistry and multiple physiological functions. It is a natural biomaterial, which has many responsibilities in the body, such as aiding cellular activity and providing an organized matrix in most tissues including skin.

Commercially manufactured Type I collagen sheets has been used for wound coverage. The following are a few quotes from the literature about commercially available collagen and its uses in wound healing, especially in Burns.

Journal name : British Journal of Community Nursing

Edition : 2005 Sep.10(9): S31-4

Authur name : King S et al, Basingstoke, UK.

Topic : Catrix: an easy-to-use collagen treatment for wound healing.

Collagen plays a major role in wound healing. Its presence is important in all stages of the healing process. Catrix is a new collagen wound-healing powder that has been shown to be effective in the treatment of wounds healing by secondary intent such as pressure ulcers, venous stasis ulcers and diabetic ulcers as well as **second-degree burns** and post-radiation dermatitis.

Catrix has also been shown to be effective in the treatment of wounds unresponsive to conventional treatments. It promotes the

growth of fibroblasts and keratinocytes in the wound, prevents loss of fluid from the wound and protects the wound from bacterial infections and other agents. Catrix is biodegradable and therefore does not require removal from the wound bed before re-application.

Journal name : Burns

Edition : 1990 Dec;16(6):457-61

Authur name : Yang JY et al,

Linkou Burn Unit, Department of Plastic Surgery, Chang Gung Memorial Hospital, Taipei, Taiwan, Republic of China.

Topic : Clinical application of collagen sheet, YCWM, as a burn wound dressing.

In the Linkou Burn Unit, a recently developed new wound dressing derived from porcine skin was evaluated. This newly designed porcine dressing, called young collagenous wettable membrane (YCWM), was developed by the staff of the Department of Cellular and Molecular Biology of Chang Gung Memorial Hospital. Many specific characteristics, such as negligible antigenicity, semitransparency, sterilizability, good pain relief and low costs, have been associated with it. The results of a clinical trial on 59 wounds on 50 burn patients proved encouraging. Some disadvantages such as maceration and delayed eschar separation were noted. They

concluded that YCWM is suitable for the treatment of the clean, dry donor sites and **superficial partial skin loss burn wounds** of non-infected, non-immunocompromised patients.

Journal name : Aktuelle Traumatol

Edition : 1992 Oct.22(5):214-8

Authur name : Goudarzi YM, Khodadadyan C, Hertel P

Topic : Clinical experience with collagenous wound dressing in severe traumatic soft tissue injuries

They treated 34 patients during 1987-1990 with a collagen wound dressing. Eleven patients had traumatic soft tissue defects, 10 patients had 3 degrees-grade open fractures, 7 patients had infected soft tissue wounds and 6 patients had **deep 2nd degree and 3rd degree burns**. Their clinical experience confirmed the excellent clinical experimental results of collagen wound dressings. In all cases after 4 until 6 days of treatment, good granulation and vascularisation of the wound bed was obtained, so that a skin transplant could be performed, which in all cases healed primarily. Moreover, the wound dressing had a **good antibacterial effect** and **integrated actively in the wound healing process.**

Journal name : Int. J Tissue React

Edition : 1992;14 Suppl:27-34

Authur name : Mian E, Martini P, Beconcini D, Mian M

Dermatological clinic, University of Milan, Italy.

Topic : Healing of open skin surfaces with collagen foils.

Applications of Condress (patented sheets of pure bovine collagen) on open skin surfaces (30 cases of "ulcus cruris", 5 cases of decubitus, and malum perforans; 10 cases of **full-thickness burns**) were examined in a controlled trial. Quantification of regeneration speed, macro-photographic survey of granulation tissue and epithelial border, thermographic and chromometric evaluation of the skin microcirculation, and histological observation of regenerating tissues, were the parameters used. The following results were obtained: marked reduction of healing time, different aspects of the granulation-tissue responses, different times of topical collagenolysis, increased vascular perfusion, histological activation of angiogenesis, fibrogenesis, histiomacrophage function and superficial absorption. The employment of Condress in burn areas seems to be highly promising.

Journal name: Zhonghua Zheng Xing Shao Shang Wai Ke Za Zhi

Edition : 1993 Jul. 9(4):284-5, 319.

Authur name : Gao ZR et al.

Department of Burn Surgery, Affiliated Hospital of Qinghai Medical College.

Topic : Early coverage of **deep partial-thickness burn wound** with porcine dermal collagen membrane. An experimental study

Collagen was extracted by pepsin digestion from porcine skin and collagen membrane was prepared by salt precipitation. Collagen membrane as a wound dressing was evaluated in a deep partial-thickness burn wounds in a rat model. Burn wound, 4 x 4 cm, were inflicted by exposing skin to 75 degrees C for 15 seconds followed by de-epithelization. Wound healing was assessed by plenimetry of epithelization on day 10 postwounding. Open wounds exhibited a re-epithelialization of 24% of wound area. **Collagen membrane dressing significantly improved the healing rate to approximately 70% of wound area.**

PATIENTS AND METHODS

This Prospective Randomized controlled study was conducted in the **Department of Burns, Plastic & Reconstructive Surgery** in the Government Kilpauk Medical College Hospital, during the period of *April 2004 to March 2006* for 2 years.

Most, if not all the burns victims in this city are being brought to this hospital and the study was conducted on these patients. The study was designed to test the efficacy of Type I Collagen dressing in hastening wound healing.

To start with, a **protocol** was formulated and **proforma** chart constituted. According to the protocol, burns patients on arrival to the hospital, were resuscitated and their general condition was stabilized. Then they were assessed clinically by the Burns Surgeon as to:

- % Body Surface Area involvement – using Lund & Browder Chart
- The Degree of Burns
- Whether to be treated as Out Patient or In Patient
- Mode of treatment – collagen dressing or conventional method

Suitable samples were selected as per the inclusion criteria and necessary exclusions were made as per the exclusion criteria given below:

Inclusion criteria

- Patients who sustained burns in 10 to 40% of Body Surface Area were included in the study.
- Patients with Superficial Second degree burns were included. These wounds are expected to heal completely within 3 weeks without any surgical intervention.
- Patients who were of age below 40 years were included in the study.
- Patients who came to the hospital within 24 hours of sustaining the burns were included.
- Patients who sustained burns over extremities & body were preferred.
- Patients who were literate & who were expected to come for regular follow-up were preferred.

Exclusion criteria

- Patients with more than 40% BSA burns were excluded from the study because of prevailing high mortality rate.
- Patients with less than 10% BSA burns were also excluded, because they were treated as Out patients and they were not expected to come for regular follow-up.
- Deep second degree & third degree burns were excluded, since these wounds will heal only with Partial thickness skin grafting.
- Elderly people were excluded due to comorbid conditions coming into play in them, which might alter the wound healing.
- Patients who came 24 hours after sustaining the injury were excluded since these wounds might have already become infected. Some of these patients might have been treated outside & already become unsuitable for collagen application because of the previous treatment modality followed earlier.
- Patients who were not expected to come for regular follow-up were excluded from the study.

The patients thus selected were enrolled into the study along with their consent. Thus a total of 100 patients were studied in which 50 patients who were **randomly allocated** into the **Experimental group** & were treated with Collagen dressing while 50 others of the **Control group** were treated with conventional dressing with Silver Sulpha Diazene ointment, gauze-pad & bandage dressing.

All the patients were admitted to the burns ward. The admission policy prevailing in our hospital was that burns patients with more than 10% BSA involvement were to be treated as In patients.

Treating the control group

The patients were resuscitated with IV fluids and their general condition improved. They were kept nil per oral. They were taken to the Burns operation theatre. Under anaesthesia, the dead skin was pealed off and the wound was cleaned well with normal saline. No antiseptics were used over the wound. Silver sulpha diazene ointment was applied over the cleaned wound and an occlusive dressing was applied with gauze-pad and roller bandage. They were brought to the wards. Oral fluids were started as per the general condition.

The patients were asked to take bath with liquid soap, once in every two days and then the dressings were changed along with the application of ointment.

Treating the Experimental Group

The patients were resuscitated with IV fluids and their general condition improved. They were kept nil per oral. They were taken to the Burns operation theatre. Under IV sedation, the dead skin was pealed off. The wound was cleaned well with normal saline.

Two types of Type I collagen dressings were used. Wet collagen sheets were washed well with normal saline and then applied over the wound. Dry collagen sheets were applied over the wound without washing. This is one of the advantages of the dry collagen. Both of them were not meshed. The collagen sheets were gently spread evenly over the skin wound with the back of the dissecting forceps. The collagen dressing was allowed to dry. The collagen gets adherent to the skin wound in few hours. The patient was brought to the wards and was asked not to move till the collagen dries off. Slowly the patient was mobilized. They were started on oral fluids first and normal diet was resumed as decided by the Burns Surgeon.

The patients were asked to take bath after 12 to 14 days. The applied collagen dressing was allowed to peel off by itself after the wound had fully epithelialized and healed. Sometimes the collagen might have to be trimmed when it does not come off by itself.

Antibiotics were prescribed to the patients according to the Antibiotic schedule of our burns unit. First, antibiotics were started empirically. Then the antibiotics were changed every weekly, according to the prevailing strain of bacterium and its sensitivity.

Within a few days, when they were fit for discharge as assessed by the Burns Surgeon, they were discharged. They were advised regular follow-up in the Out Patient department.

All these patients were followed up regularly in the OPD. The control group was reviewed once in every two days for changing the dressing along with application of ointment. For the next two weeks Post-Burn, all the patients were reviewed once weekly. Any difference in wound healing was managed appropriately.

After the wound had completely epithelialized and healed well, the patients were advised to review once a month for one year in order to assess and manage any late complications like hypertrophic scars, contractures, & Keloids.

All the data were collected in the Proforma. They were formulated in a Master chart given behind. The clinical data thus formulated were assessed.

- The efficacy on wound healing was assessed according to the time taken in both groups for complete wound healing.
- The ability to prevent infection was assessed clinically in the Experimental group by the collection of pus underneath the collagen, erythema of the skin, and systemic manifestations like fever. If pus collected under collagen dressing, it was drained and another collagen sheet was reapplied over the previous one. In the control group, it was assessed by taking bacterial swab after 24 hours, 7 days (and 14 days if needed).
- The effect on the morbidity of the patients was assessed by Pain experienced by the patient (subjective), Oozing, Smell, early mobilization and the ability of the patient to take care of his day-to-day activities by himself.
- The cost-effectiveness was assessed by the number of dressings needed to apply for the patients. Generally, the experimental group needed only a single sitting of dressing with the collagen material. Whereas the control group needed dressing once in every two days as long as the wound gets completely epithelialized.

OBSERVATION & RESULTS

Most of the patients in the experimental group showed accelerated wound healing as seen from the table. In more than 90% of cases, the burn wound completely healed within 12-14 days. In more than 50% of the Control group, wound healing got delayed.

The most common inhibiting factor causing the delay in wound healing was INFECTION. 96% of the Experimental group had no infection. In the control group, 52% got infected with the prevailing hospital acquired strains of bacteria.

28% of the Experimental group experienced pain due to the burn wound & it progressively improved in its severity. 88% of the Control group experienced pain. This is more due to repeated dressing changes. About 70% in the Control group suffered from increased oozing & smell from the wound whereas the Experimental group was devoid of these problems.

Most of the Experimental group could be mobilized early and they took care of their daily needs by themselves. The patients of the Control group had difficulty in early mobilization & were dependent on their close relatives for their personal needs in their early post burn days.

One patient in the Experimental group expired on the 3rd post burn day due to MODS. His urine output decreased first and Urea & creatinine rose slowly. The renal failure was managed but in vain. Following this, his general condition slowly deteriorated and he expired. The possible mode of death was declared as - due to Septicaemia.

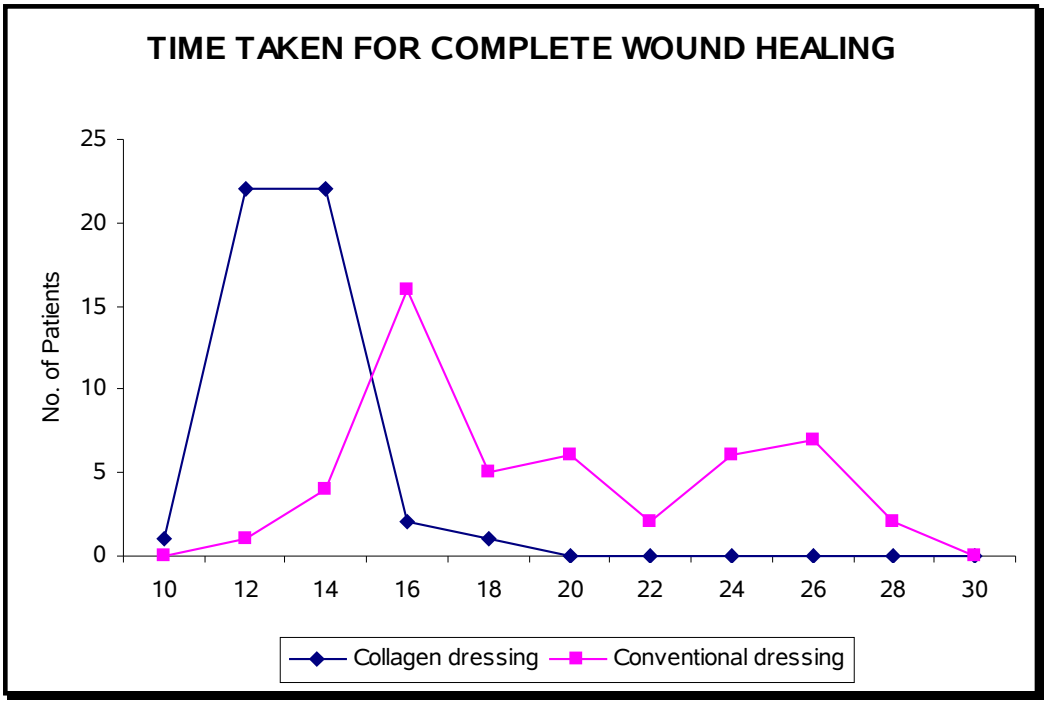
One patient each from both the groups lost follow-up. They could not be reached by post & person, in spite of repeated such attempts. They happened to be living in rented houses. They shifted their residence during the follow-up period after the unfortunate fire accident.

Three patients in the control group underwent Split Thickness Skin grafting because of delayed wound healing & took more than double the time for completion of wound healing process.

The results of the study were tabulated as follows:

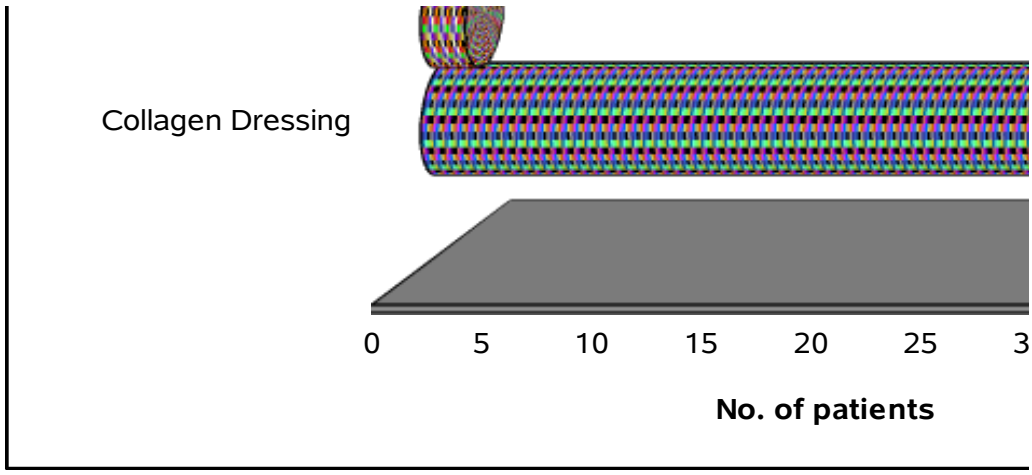
TIME TAKEN FOR COMPLETE WOUND HEALING

No. of days	Collagen dressing	Conventional dressing
10	1	-
12	22	1
14	22	4
16	2	16
18	1	5
20	-	6
22	-	2
24	-	6
26	-	7
28	-	2
30	-	-



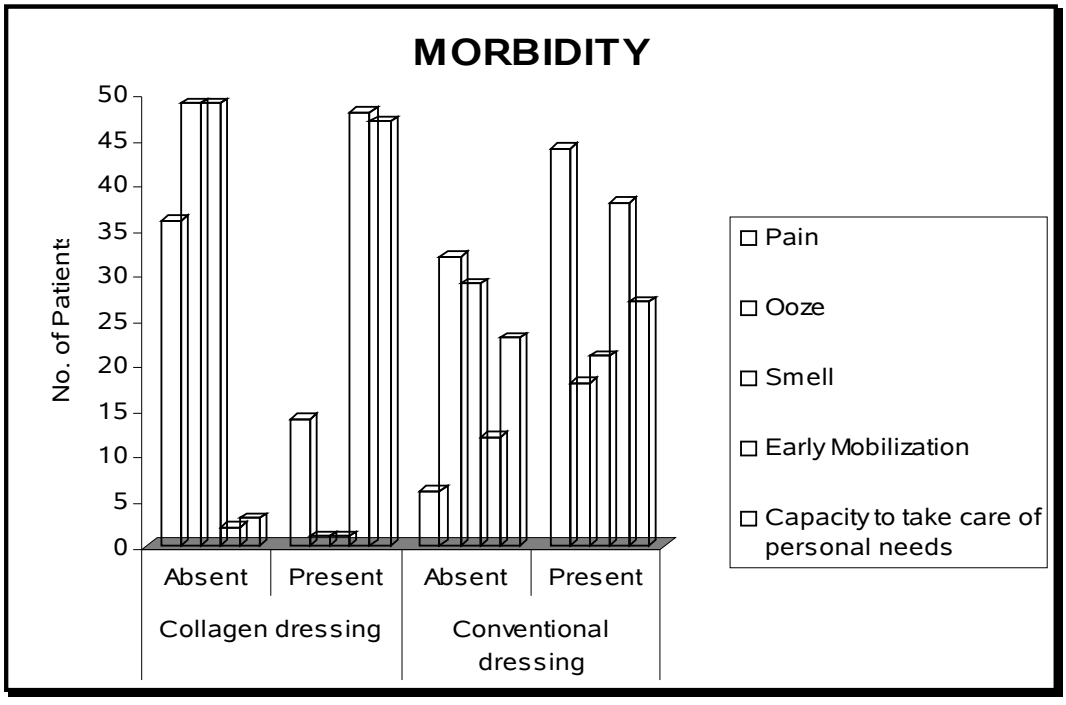
INFECTION

Infection	Collagen Dressing	Conventional Dressing
Absent	48	24
Present	2	26



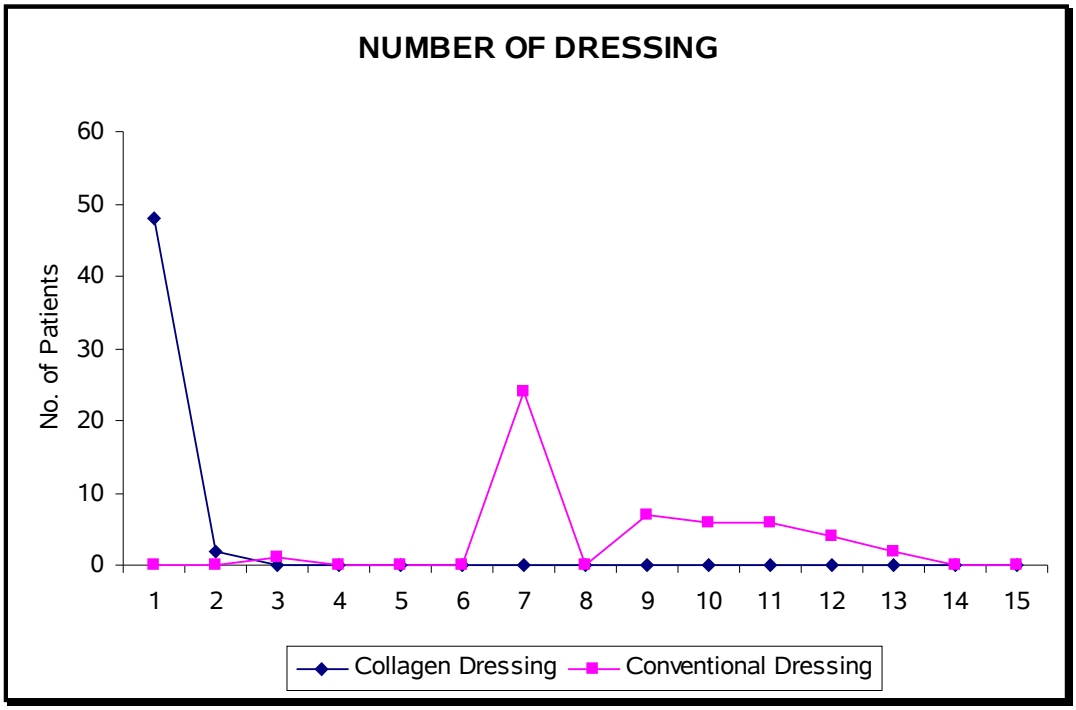
MORBIDITY

	Collagen dressing		Conventional dressing	
	Absent	**Present**	**Absent**	**Present**
Pain	36	14	6	44
Ooze	49	1	32	18
Smell	49	1	29	21
Early Mobilization	2	48	12	38
Capacity to take care of personal needs	3	47	23	27



NUMBER OF DRESSING

No. of Dressing	Collagen Dressing	Conventional Dressing
1	48	-
2	2	-
3	-	1
4	-	-
5	-	-
6	-	-
7	-	24
8	-	-
9	-	7
10	-	6
11	-	6
12	-	4
13	-	2
14	-	--
15	-	-



DISCUSSION

This Prospective Randomized Control study was conducted to know the efficiency of Type I Collagen Wound Cover dressing as compared to the Conventional modality of dressing with ointment, gauze-pad & bandage.

With respect to the effect on wound healing:

90% of the Experimental group attained complete wound healing in 12 -14 days whereas in the Control group, it took 16 -26 days even in the absence of infection. It was already proved beyond doubt by Winter in 1962 that **the rate of epithelialization under an occlusive dressing was twofold than that of the wounds left undressed.**

Here, even though both type of wound dressings used in this study are Occlusive dressings, they showed difference among themselves in acceleration of wound healing. This is due to the inherent properties of the Type I Collagen dressing. The collagen sheet when applied over the wound forms a base for the epithelialization to occur. This is not provided by the ointment, gauze-pad & bandage dressing. Collagen withholds the vital exudates coming from the wound, which is rich in cytokines that accelerate

wound healing in an acute wound. This exudate gets wigged away from the wound in the conventional dressing.

The burn wounds of the patients in the control group were invariably contaminated due to bacterial colonization as compared to the experimental group. 52% of the control group had wound infection where as 96% of the experimental group did not. Infection was the most important factor that delayed the healing of wound in the control group.

The morbidity suffered by the control group was worth mentioning. These patients had wound infection, increased oozing & smell from the wound. They experienced more pain, especially while taking bath and changing the dressing. They could not be mobilized early and so this led to these patients being dependant on their close relatives for their daily personal needs. The experimental group did well in this respect. They had no dressing changes; they experienced less pain. They had no or least ooze & smell from the wound. They could be mobilized early. These patients were able to take care of themselves without the help of their close relatives.

Regarding the cost factor, even though Type I Collagen dressing appeared costly initially, this actually is less when compared to the control group. The cost of the dressing materials, the man-power for its preparation & application, the income loss incurred by the close

relatives when they had to accompany the patient to the department for dressing – all taken together works out to be much more costlier when compared to the cost of the collagen treatment. The comfort experienced by the collagen group is the most attractive aspect to be stressed in this study.

PITFALLS OF THE STUDY

This prospective randomized control study had its own pitfalls.

- Blinding was not possible in this study because the difference in treatment is very well obvious. Therefore Subject variation bias is inevitable.
- Two patients lost follow-up. This happened and was inevitable in spite of all measures taken to prevent this by sending letters and persons.
- One patient in the Experimental group expired on the 3rd Post burn day due to MODS. This was paradoxical when compared to other patients in the experimental group who did well when compared to the control group.

CONCLUSION

Collagen wound cover dressing, when compared to Conventional dressing with Silver Sulpha Diazene ointment, gauze-pad & bandage,

- Accelerates the wound healing and thereby reduced the hospital stay
- Prevents the incidence of Infection
- Reduces the morbidity suffered by the patients
- Cost effective

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GOVERNMENT KILPAUK MEDICAL COLLEGE

Kilpauk, Chennai – 10.

DEPARTMENT OF SURGERY

A PROSPECTIVE RANDOMISED CONTROL STUDY ON COMPARISON OF WOUND HEALING WITH COLLAGEN DRESSING & CONVENTIONAL DRESSING IN BURNS PATIENTS

PROFORMA

Serial No.:

Name : Age : Sex :

AB No. : Educational Status :

% BSA Burns : Address for Communication with Phone No.

Degree of Burns :

Etiology : | Burns | Scalds | Electric | Radiation |

Type of Injury : | Accident | Suicide | Homicide |

Time of Accident :

Time of Admission:

Time of Application of Dressing

Type of Dressing: | Collagen | Conventional |

Time taken for Complete Healing : [ ] Days

Wound Infection : Present / Absent

Morbidity : Pain Present / Absent

Ooze Present / Absent

Smell Present / Absent

Mobilization : Early / Late

Personal Care : Self / Help

Number of Dressing Made : [ ]

Remarks (if any)

ABBREVIATIONS

AB no.	:	**A**ccidental **B**urns Number
IP no.	:	In Patient Number
% BSA	:	Percentage of **B**ody **S**urface **A**rea
CWH	:	Time taken for **C**omplete **W**ound **H**ealing
Inf.	:	Infection
Pn	:	Pain
OZ	:	Ooze
Sm	:	Smell
EM	:	**E**arly **M**obilization
DA	:	Able to take care of their **D**ay-to-day **A**ctivities
No. Dr	:	Number of **Dr**essings required
M	:	Male
F	:	Female
P	:	Present
A	:	Absent

MASTER CHART

.	Name	AB No.	IP No.	Age	Sex	%BSA	Dressing		CWH	Inf	Morbidity				
											Pn	Oz	Sm	EM	DA
	Subramani	316/04	7158	24	M	24%	-	Collagen	12	A	A	A	A	P	P
	Susheed	330/04	7526	35	F	20%	Ointment	-	14	A	P	A	A	P	P
	Eswari	342/04	7841	34	F	20%	-	Collagen	14	A	P	A	A	P	P
	Govindan	356/04	7926	17	M	11%	Ointment	-	16	A	A	A	A	P	P
	Kasthuri	366/04	8346	35	F	27%	-	Collagen	12	A	A	A	A	P	P
	Chandran	380/04	8623	26	M	33%	-	Collagen	12	A	A	A	A	P	P
	Manohar	392/04	8956	25	M	20%	Ointment	-	24	P	P	P	P	A	A
	Jamuna	407/04	9287	14	F	23%	-	Collagen	14	A	P	A	A	P	P
	Divya	418/04	9658	12	F	17%	-	Collagen	12	A	A	A	A	P	P
	Thirumaran	432/04	10042	24	M	15%	Ointment	-	16	A	P	P	A	P	P
	Peter Muthu	445/04	10532	35	M	17%	Ointment	-	26	P	P	P	P	A	A
	Moorthy	449/04	10823	18	M	26%	Ointment	-	18	P	P	P	A	A	P
	Ayesha	460/04	11411	25	F	34%	-	Collagen	14	A	A	A	A	P	P
	Kulshar Begam	468/04	11625	23	F	35%	-	Collagen	14	A	P	A	A	P	P
	Thirumaran	480/04	11862	30	M	14%	Ointment	-	26	P	P	P	P	A	A
	Narasimhalu	489/04	12025	25	M	25%	Ointment	-	16	A	P	A	A	P	P
	Kaliappan	498/04	12563	37	M	16%	-	Collagen	14	A	P	A	A	P	P
	Maheshwari	511/04	13241	11	F	14%	-	Collagen	12	A	A	A	A	P	P
	Praveen	532/04	13921	21	M	30%	Ointment	-	14	A	A	A	A	P	P
	Gayathri	541/04	14354	28	F	30%	Ointment	-	16	A	P	A	A	P	P
	Kuppan	560/04	14586	30	M	17%	Ointment	-	20	P	P	A	P	P	A
	Maragadham	561/04	14602	10	F	15%	-	Collagen	14	A	A	A	A	P	P
	Nazeema	569/04	15245	32	F	30%	-	Collagen	12	A	P	A	A	P	P
	Prabakaran	580/04	15864	35	F	10%	Ointment	-	12	A	A	A	A	P	P
	Kavya	591/04	16260	12	F	18%	-	Collagen	12	A	A	A	A	P	P
	Suresh#	625/04	17350	21	M	26%	-	Collagen	xx	A	P	A	A	A	A
	Nirmala	663/04	17865	28	F	18%	Ointment	-	24	P	P	P	P	A	A
	Prabha	689/04	18562	30	F	18%	Ointment	-	16	A	P	A	A	P	P
	Valli	709/04	19245	26	F	15%	-	Collagen	12	A	A	A	A	P	P
	Selvi	722/04	19952	36	M	10%	Ointment	-	16	A	P	A	A	P	P
	Vijayalakshmi	739/04	20468	24	F	34%	-	Collagen	14	A	P	A	A	P	P
	Balaraman	751/04	20951	22	M	22%	-	Collagen	18	P*	P	A	A	P	A
	Kanthan	762/04	21342	25	M	17%	Ointment	-	14	A	A	A	A	P	P
	Nawaab	778/04	21867	35	M	10%	Ointment	-	16	A	P	A	A	P	P
	Karunakaran	791/04	22243	32	M	12%	-	Collagen	14	A	A	A	A	P	P
	Sivagami	799/04	22645	20	F	30%	-	Collagen	12	A	A	A	A	P	P

.	Name	AB No.	IP No.	Age	Sex	%BSA	Dressing		CWH	Inf	Morbidity				
											Pn	Oz	Sm	EM	DA
	Komalavalli	807/04	22948	26	F	12%	Ointment	-	16	A	P	P	A	A	P
	Dilli Babu	819/04	23192	5	M	18%	-	Collagen	**	P*	P	P	P	A	A
	Sujeetha	830/04	23564	20	F	26%	-	Collagen	14	A	A	A	A	P	P
	Ashok Kumar	841/04	23951	4	M	31%	Ointment	-	26	P	P	P	P	A	A
	Amul	857/04	24234	21	F	18%	Ointment	-	28	P	P	P	P	A	A
	Parimala	868/04	24685	32	F	13%	-	Collagen	12	A	A	A	A	P	P
	Mathivanan	879/04	24962	3	M	20%	-	Collagen	12	A	A	A	A	P	P
	Ramesh	891/04	25215	22	M	30%	Ointment	-	**	P*	P	P	P	A	A
	Neelavathi	898/04	25496	25	F	18%	-	Collagen	14	A	A	A	A	P	P
	Ramu	906/04	25798	11	M	19%	Ointment	-	20	P	P	A	P	P	A
	Karuppiah	916/04	26004	35	M	14%	-	Collagen	16	A	P	A	A	P	P
	Babu Sekar	924/04	26289	38	M	10%	Ointment	-	24	P	P	P	P	A	A
	Sudha	939/04	26541	27	F	24%	-	Collagen	14	A	A	A	A	P	P
	Shakthi Banu	953/04	26983	24	F	30%	-	Collagen	16	A	P	A	A	P	P
	Devi	14/05	356	24	F	17%	Ointment	-	30	P	P	P	P	A	A
	Thilaga	26/05	543	25	F	35%	-	Collagen	14	A	A	A	A	P	P
	Selvaraj	34/05	856	35	F	12%	Ointment	-	24	P	P	P	P	P	A
	Sahul Hameed	47/05	1131	29	M	11%	Ointment	-	20	P	P	A	P	P	A
	Banu	59/05	1523	28	F	35%	Ointment	-	18	A	A	A	P	P	P
	George	74/05	2013	37	M	15%	Ointment	-	22	P	P	A	P	P	A
	Uma	76/05	2096	28	F	25%	Ointment	-	16	A	P	A	A	P	P
	Vinodh	88/05	2543	12	M	15%	Ointment	-	26	P	P	P	A	P	A
	Jabesa	98/05	2956	4	F	14%	-	Collagen	12	A	A	A	A	P	P
	Indira	106/05	3212	35	F	27%	-	Collagen	14	A	A	A	A	P	P
	Moses	121/05	3689	9	M	10%	Ointment	-	16	A	P	A	A	P	P
	Suriya	128/05	3956	22	F	18%	Ointment	-	14	A	A	A	A	P	P
	Padmini	138/05	4275	38	F	35%	-	Collagen	12	A	P	A	A	P	P
	Shanmugam	147/05	4738	25	M	29%	-	Collagen	14	A	A	A	A	P	P
	Anitha	155/05	5049	16	F	25%	Ointment	-	16	A	P	A	A	P	P
	Jayakumar	168/05	5568	9	M	22%	-	Collagen	14	A	A	A	A	P	P
	Baranidaran	181/05	5946	36	M	24%	Ointment	-	18	A	P	A	A	P	P
	Muthulakshmi	193/05	6326	17	F	24%	-	Collagen	14	A	A	A	A	P	P
	Devaraj	203/05	6714	37	M	25%	Ointment	-	16	A	P	A	A	P	P
	Sangeetha	214/05	6998	22	F	14%	-	Collagen	12	A	A	A	A	P	P
	Rizwana	221/05	7342	25	F	11%	Ointment	-	28	P	P	P	P	A	A
	Kalpana	229/05	7752	3	F	15%	-	Collagen	12	A	A	A	A	P	P
	Vijayakumar	235/05	7987	30	M	12%	-	Collagen	12	A	P	A	A	P	P
	Saraswathi	243/05	8205	37	F	10%	Ointment	-	24	P	P	P	A	P	A
	Lakshmi	254/05	8512	30	F	29%	-	Collagen	14	A	A	A	A	P	P

.	Name	AB No.	IP No.	Age	Sex	%BSA	Dressing		CWH	Inf	Morbidity				
											Pn	Oz	Sm	EM	DA
	Vanitha	262/05	8883	19	F	27%	-	Collagen	14	A	A	A	A	P	P
	Nagarajan	275/05	9005	29	M	10%	Ointment	-	26	P	P	P	A	P	A
	Rekha	283/05	9346	22	F	19%	-	Collagen	12	A	A	A	A	P	P
	Vennila	296/05	9676	20	F	23%	-	Collagen	14	A	A	A	A	P	P
	Chandrasekar	302/05	9856	25	M	17%	Ointment	-	16	A	P	A	A	P	A
	Suriya	316/05	10223	20	F	19%	-	Collagen	12	A	A	A	A	P	P
	Kalyani	329/05	10678	35	F	17%	Ointment	-	22	P	P	A	P	P	A
	Sureka	338/05	10978	35	F	18%	Ointment	-	16	A	P	A	A	P	P
	Girija	346/05	11143	32	F	35%	-	Collagen	14	A	A	A	A	P	P

85	Vignesh	354/05	11412	2	M	13%	Ointment		18	A	P	A	A	P	P	7
86	Viswanathan	364/05	11706	28	M	26%	-	Collagen	12	A	A	A	A	P	P	1
87	Baskaran	371/05	11958	34	M	18%	Ointment	-	16	A	P	A	A	P	P	7
88	Uma	385/05	12265	19	F	16%	Ointment	-	24	P	P	A	P	P	A	11
89	Nirmala	393/05	12512	20	F	25%	-	Collagen	14	A	A	A	A	P	P	1
90	Veeraperumal	402/05	12864	23	M	30%	-	Collagen	12	A	A	A	A	P	P	1
91	Radha	415/05	13142	20	F	25%	Ointment	-	26	P	P	A	A	P	P	10
92	Vadivu	426/05	13546	38	F	25%	-	Collagen	12	A	A	A	A	P	P	1
93	Raja	439/05	13891	38	M	10%	-	Collagen	10	A	A	A	A	P	P	1
94	Devika	451/05	14124	24	F	23%	Ointment	-	20	P	P	A	P	P	A	9
95	Kalyani	459/05	14356	22	F	36%	-	Collagen	12	A	A	A	A	P	P	1
96	Dhanalakshmi	465/05	14625	32	F	23%	Ointment	-	18	P	P	A	A	P	P	9
97	Karthika	471/05	14876	17	F	14%	Ointment	-	26	P	P	P	P	P	A	12
98	Rasool Beevi	478/05	15042	28	F	37%	-	Collagen	14	A	P	A	A	P	P	1
99	Sushmitha	497/05	15345	11	F	32%	Ointment	-	20	P	P	A	P	P	P	9
100	Gopinath	503/05	15875	15	M	22%	Ointment	-	16	A	P	A	A	P	P	7